EXHIBIT 48

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL CASES

MDL NO. 16-2738 (FLW) (LHG)

RULE 26 EXPERT REPORT OF
ELLEN BLAIR SMITH, MD

Date: November 16, 2018

Ellen Blair Smith, MD

As a physician who specializes in the treatment of women with cancer (including ovarian cancer), I was asked to provide professional opinions on the question of whether the genital use of talcum powder products can cause ovarian cancer. I was also asked, if I found this to be the case, to further provide opinions on the biological mechanism(s) for this effect.

BACKGROUND AND QUALIFICATIONS

My name is Ellen Blair Smith. My attached CV reports my education and medical training. I practiced gynecologic oncology in Charlottesville, Virginia from July 1984 until February 1987 as an assistant professor at the University of Virginia. I then left academic medicine to open my own private practice of gynecologic oncology in Austin, Texas. That practice involved care of women known or suspected to have gynecologic cancers and continued for more than 28 years. During these years, I was responsible for all aspects of the care of hundreds of women with epithelial ovarian cancer. That care involved diagnosis, preoperative, surgical, and postoperative care, chemotherapy selection and administration and post-treatment care and surveillance. All too often post-treatment surveillance led to the diagnosis of recurrent cancer and the treatment cycle resumed. All too often, after months or years (up to 21 years of care for one patient), I provided end-of-life care for my patients.

My dissatisfaction with the inadequacies of screening systems to detect ovarian cancer early led me to follow enthusiastically the discoveries of genes that increase the risk of ovarian cancer and to aggressively promote the detection of such genes. Before these tests were commercially available, I worked with geneticist-physicians at the University of Pennsylvania and Duke University to detect these genes in my patients with ovarian cancer and their daughters. I was an early advocate of risk-reducing salpingooophorectomy and lectured throughout Texas by invitation of the Texas Medical Association. In 2004, Myriad Genetics (which had patented the BRCA test) asked me to be its first gynecologic oncologist speaker. Until roughly 2011, I delivered many lectures to gynecologic colleagues throughout the US.

In November 2001, I took a leave of absence and moved to Paris, France, with my children while my husband pursued a Guggenheim fellowship there. While there, I returned to the US to attend the Society of Gynecologic Oncologists to hear the latest research in ovarian cancer presented. I also attended a European Cancer conference in Paris and was excited to first hear the results of the Scottish Randomised Trial in Ovarian Cancer (SCOTROC), a large international randomized trial comparing two different chemotherapy regimens for the treatment of epithelial ovarian cancer ovarian cancer trial in which I enrolled patients. I returned to my practice in August of 2002.

To enhance the end of life care of my gynecologic oncology patients, I pursued further education in Hospice and Palliative Care, passing the written examination to become board certified in 2010. I retired from my gynecologic oncology practice in December of 2015. In April of 2017, I returned to patient care as medical director of Halcyon Home Hospice. In my role with a hospice organization, I continue to care for patients with ovarian and other cancers. My CV is attached as Exhibit A.

METHODOLOGY

In preparing this report, I began with a comprehensive review of the medical literature. I relied on PubMed searches on many topics, including talc and ovarian cancer, as well as searched authors. I then read many of the references of the articles cited in those papers. I sometimes followed this research with searches on Google or Google Scholar on the same subjects to assure that I had found all relevant references. This literature included epidemiological studies, review articles, mechanistic articles and opinion articles on this topic and related subjects. I additionally reviewed information, including Johnson & Johnson and Imerys company documents that I either requested or considered relevant to my opinions. These were provided by plaintiffs' attorneys. Finally, I drew on my own educational resources, as well as my education, training, and experience caring for patients with ovarian cancer This is the same methodology and scientific rigor that I have used regularly in my professional career and clinical practice, to explore and understand a topic of interest.

OVERVIEW OF OVARIAN CANCER

Cancers of the ovary may arise from the epithelium/mesothelium covering the ovary, called epithelial ovarian cancer (EOC); from the oocytes of the ovary, called germ cell tumors; or, more rarely, from the hormone-producing cells of the ovary, the sex cord-stromal tumors. This report addresses EOC, the type of ovarian cancer associated with talcum powder exposure.

Pathogenesis

The history as to the origin of ovarian cancer must be divided into before 2008 and after 2008. Before 2008, incessant ovulation and the repair of the monthly breaks in ovarian surface epithelium was believed to be responsible for EOC. (Fathalla 1971). That more DNA errors would be generated with more ovulation defects made intuitive sense and seemed to be supported by the epidemiologic evidence of higher parity (ovulation free windows) decreasing risk of EOC (La Vecchia 2017). Furthermore, the first generation of high estrogen oral contraceptives that blocked ovulation also decreased ovarian cancer. (Havrilesky et al. 2013) Levanon proposed that EOC is, in fact, two different diseases with two etiologies; the premalignant state of Type II was, as yet, unidentified. Budding molecular data support this division. (Levanon, Crum, and Drapkin 2008).

Until 2008, EOC was thought distinct from fallopian tube cancer and primary peritoneal cancer. While the cell of origin for all these cancers appears similar, many papers were published and conventions defined to separate them. The pioneering work of scientists/physicians at Brigham and Women's and the Dana Farber revealed that many EOCs arise in the fallopian tube and metastasize to the ovary and/or peritoneum, at least in women who harbor genetic homologous repair defects. (Levanon, Crum, and Drapkin 2008). Both Fathalla and the researchers at Brigham and Women's have updated and more clearly defined their hypotheses in light of the increased role of fallopian tube epithelium in EOC and growing molecular data. (Levanon, Crum, and Drapkin 2008; Fathalla 2013). Dubeau and Drapkin include and support the role of extrauterine Mullerian epithelium, as well as tubal and ovarian epithelium, in their hypotheses of pathogenesis of EOC. (Dubeau and Drapkin 2013). For our purposes, we consider epithelial

cancers of the ovary, fallopian tubes, and peritoneum to be a single entity. All are associated with talcum powder usage

The quest for a molecular understanding of the ways EOC arise is ongoing, but has also been described extensively. There are certain factors that can initiate the cascade of DNA changes that cause unregulated proliferation, acquisition of more DNA damage, and inhibition of programmed cell death (apoptosis) - the normal fate of abnormal cells in a healthy system. For example, loss of TP53 (a gene essential for regulating cell division and preventing tumor formation), function has been shown to appear early in the genesis of serous EOC. (Chien et al. 2015).

Risk Factors

Generally accepted risk factors for EOC, in addition to talcum powder and asbestos, include inherited gene mutations, family history, obesity, nulliparity, advanced age, history of endometriosis, infertility, polycystic ovarian syndrome, intrauterine devices, pelvic inflammatory disease, early menarche and late menopause. Additionally, there are factors that are recognized as protective. These include tubal ligation/sterilization (TS), oral contraceptive use, salpingectomy, salpingo-oophorectomy, hysterectomy, and breast feeding. (Hunn and Rodriguez 2012; Mallen, Townsend, and Tworoger 2018; Park et al. 2018; Folkins et al. 2018). Risk factors are not mutually exclusive. They can be cumulative, additive, and synergistic. (Vitonis, Titus-Ernstoff, and Cramer 2011; S. Wu et al. 2018).

Inherited gene mutations, such as BRCA-Fanconi anemia pathway and Lynch syndrome mismatch repair genes, are discussed in another section.

The Ovarian Cohort Consortium pooled data from 21 prospective cohort studies on 1.3 million women. (Wentzensen et al. 2016). In these studies, 5584 women were diagnosed with EOC and risk comparisons were made for parity, oral contraception use, breast feeding, age at menarche, age at menopause, menopausal HRT use, tubal ligation, endometriosis, first degree family history of breast cancer, first degree history of ovarian cancer, BMI, height, and smoking). In a group this large, histologic subclassification could be done and associations were made for serous/poorly differentiated EOC, endometrioid EOC, clear cell EOC and mucinous EOC. One thousand EOC patients had “other” or missing histologic information. Multiparity decreased risk in all ovarian cancer subtypes. Oral contraceptive use for 5 years and for 10 years decreased risk in all but mucinous tumors. Late menopause increased risk in only endometrioid and clear cell cancers.

Diagnosis

The diagnosis of EOC may occur at surgery for a pelvic mass, incidentally at surgery for another reason, or by cytologic evaluation of paracentesis of ascites.

Staging

Ovarian cancer, regardless of cell type, is staged surgically. By convention, we use International Federation of Gynecology and Obstetrics (FIGO) staging. The staging system changes every 10-

15 years as data allowing discrimination are reviewed. It was always my practice to note in a patient's chart the original stage and year of that staging versus contemporary stage.

STAGE I: Tumor confined to ovaries				
OLD			NEW	
IA	Tumor limited to 1 ovary, capsule intact, no tumor on surface, negative washings/ascites.		IA	Tumor limited to 1 ovary, capsule intact, no tumor on surface, negative washings.
IB	Tumor involves both ovaries otherwise like IA.		IB	Tumor involves both ovaries otherwise like IA.
IC	Tumor involves 1 or both ovaries with any of the following: capsule rupture, tumor on surface, positive washings/ascites.		*IC Tumor limited to 1 or both ovaries*	
			IC1	*Surgical spill*
			IC2	*Capsule rupture before surgery or tumor on ovarian surface.*
			IC3	*Malignant cells in the ascites or peritoneal washings.*

STAGE II: Tumor involves 1 or both ovaries with pelvic extension (below the pelvic brim) or primary peritoneal cancer				
OLD			NEW	
IIA	Extension and/or implant on uterus and/or Fallopian tubes		IIA	Extension and/or implant on uterus and/or Fallopian tubes
IIB	Extension to other pelvic intraperitoneal tissues		IIB	Extension to other pelvic intraperitoneal tissues
IIC	IIA or IIB with positive washings/ascites.			

Old stage IIC has been eliminated

STAGE III: Tumor involves 1 or both ovaries with cytologically or histologically confirmed spread to the peritoneum outside the pelvis and/or metastasis to the retroperitoneal lymph nodes				
OLD			NEW	
IIIA	Microscopic metastasis beyond the pelvis.		*IIIA (Positive retroperitoneal lymph nodes and /or microscopic metastasis beyond the pelvis)*	
			IIIA1	*Positive retroperitoneal lymph nodes only*
				IIIA1(i) *Metastasis ≤ 10 mm*
				IIIA1(ii) *Metastasis > 10 mm*
			IIIA2	*Microscopic, extrapelvic (above the brim) peritoneal involvement ± positive retroperitoneal lymph nodes*
IIIB	Macroscopic, extrapelvic, peritoneal metastasis ≤ 2 cm in greatest dimension.		IIIB	*Macroscopic, extrapelvic, peritoneal metastasis ≤ 2 cm ± positive retroperitoneal lymph nodes. Includes extension to capsule of liver/spleen.*
IIIC	Macroscopic, extrapelvic, peritoneal metastasis > 2 cm in greatest dimension and/or regional lymph node metastasis.		IIIC	*Macroscopic, extrapelvic, peritoneal metastasis > 2 cm ± positive retroperitoneal lymph nodes. Includes extension to capsule of liver/spleen.*

STAGE IV: Distant metastasis excluding peritoneal metastasis				
OLD			NEW	
IV	Distant metastasis excluding peritoneal metastasis. Includes hepatic parenchymal metastasis.		*IVA*	*Pleural effusion with positive cytology*
			IVB	Hepatic and/or *splenic parenchymal* metastasis, metastasis to extra-abdominal organs (including inguinal lymph nodes and lymph nodes outside of the abdominal cavity)

FIGO Ovarian Cancer Staging Effective Jan. 1, 2014[1]

Treatment

The treatment of ovarian cancer is usually straight-forward: surgically remove all the visible cancer, establish locations of invisible cancer (microscopic metastases, define best treatment and prognosis, then treat -in the majority of cases - with a taxane and a platinum chemotherapy doublet. (Vasey et al. 2004; Armstrong et al. 2006).

However, seventy-five percent of ovarian cancer cases present with metastases to the upper abdomen or beyond. Suboptimal debulking (leaving grossly visible tumor) has no survival benefit over primary chemotherapy. (Horowitz et al. 2015). The physicians at MD Anderson established a protocol for preoperative laparoscopy and the opinions of two trained gynecologic oncologists, in concert with clinical and laboratory findings, to judge whether a tumor was resectable. (Nick et al. 2015). These “debulking” surgeries are quite complex, require specialized training, and often necessitate consultation from other surgical specialties.

[1] https://www.sgo.org/wp-content/uploads/2012/09/FIGO-Ovarian-Cancer-Staging_1.10.14.pdf

Chemotherapy with a platinum and a taxane follows. These drugs may be delivered intravenously or intraperitoneally. Usually, six cycles of chemotherapy are given. Remission occurs in over 70% of patients, as evidenced by CT scans, physical examination, and CA125 (a clinically used biomarker for screening and detection) levels. Surveillance begins.

In patients with Stage III and IV (typically 75% of patients with EOC), recurrence will follow in 5-24 months. Then we evaluate again for surgery (isolated focal recurrence versus multifocal or unresectable recurrence) and additional chemotherapy. (Rasool et al. 2010; Parmar et al. 2003).

This cycle typically continues until my patient's tumor has become resistant to platinum and two other agents. At that time, the probability of her tumor responding to any standard chemotherapy is essentially nonexistent. We discuss clinical trials and/or end-of-life care. Regardless of her treatment choices, she dies in 6-12 months. Her death is protracted, usually from starvation, due to multiple bowel obstructions. Ideally, pain is controlled.

5 Year Survival Rates

The following are 5-year survival rates according to the American Cancer Society Website. As the new FIGO staging just started in 2014, 5-year data is not yet available.

I 78%

IA 93%

IB 91%

IC 84%

II 61%

IIA 82%

IIB 72%

IIC 67%

III 28%

IIIA 63%

IIIB 53%

IIIC 41%

IV 19%[2]

Modern surgery and chemotherapy have changed the natural history of ovarian cancer. Late recurrence (after 5-year) is common. Ten-year survival does not mean cure. I have personally treated late recurrences after ten years of remission. Others have reported these findings as well. (Baldwin et al. 2012; Tewari et al. 2015)

[2] https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/survival-rates.html

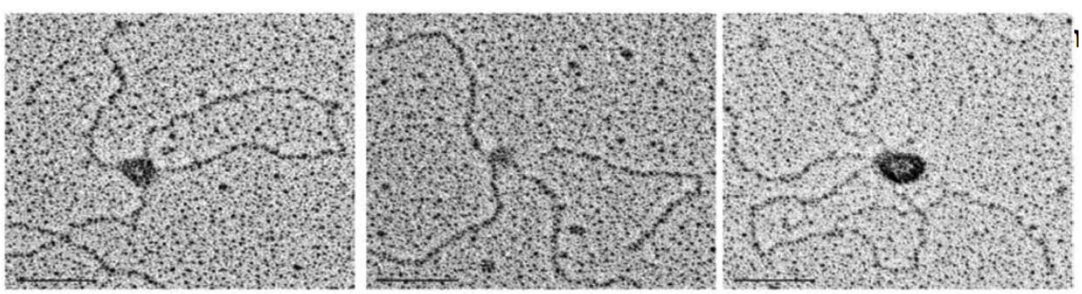
OVARIAN CANCER GENETICS

All cancer is genetic; that is, cancer involves DNA changes occurring in the chromosomes of a cell that was initially normal. For epithelial cancers, this is usually a series of mutations, DNA breaks, alterations (such as methylation), deletions, rearrangements or DNA amplification. These changes do not necessarily progress linearly. Watson reviewed some of these complexities in a recent article in Nature. (Watson et al. 2013).

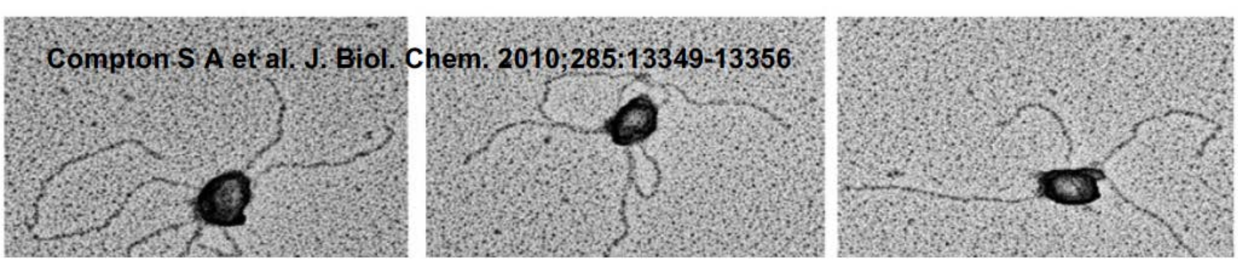
A Cancer Genome Atlas Research Network (TCGA) study published in 2011 analyzed 489 high grade serous ovarian cancers (HGSOC). Exon sequencing of 316 of these tumors was performed. It identified the nearly universal (96%) presence of somatic mutations in the gene TP53 in HGSOC. That mutation seems to be a first step towards the development of EOC. Ovarian cancers occur in <3% of women with germline, heritable TP53 mutations; breast cancer is much more frequently occurring. (K. D. Gonzalez et al. 2009). Genes in homologous repair pathway were mutated in 49% (with better prognosis for those with germline mutations as opposed to somatic mutation or methylation). The FOXM1 transcription factor network was activated in 87%. This family of genes is involved in regulating cell cycle and differential gene expression. (Hannenhalli and Kaestner 2009; X. Chen et al. 2013).

Interest in the homologous repair pathway has exploded since Mary Claire King's identification of what we now know to be the tumor suppressor gene, BRCA1. (Hall et al. 1990). Homologous DNA repair is double stranded DNA repair breaks. This pathway includes multiple genes including BRCA1, BRCA2, Rad 51B, Rad 51C, Rad 51D, BRIP1, PALB2 and others. The protein products of this family of multiple genes work together to repair DNA. (Compton, Ozgür, and Griffith 2010; Thai et al. 1998). Binding of BCDX2 or CX3 to Holliday Junction DNA CX3 (A) or BCDX2 (B) was incubated with Holliday junction templates, mounted onto carbon-coated copper grids, and rotary shadowcast with tungsten for visualization by EM. Images are shown in reverse contrast. (Compton, Ozgür, and Griffith 2010).

A



B



The ring structure in A is a complex of Rad 51C and Xrcc3. The ring structure in B is a complex of Rad 51B, Rad 51 C, Rad 51D and Xrcc2.

Germline deficiencies in any of these genes have been shown to result in an increased risk of EOC. Why? Knudson answered that in simple terms (Knudson 1971). To be born deficient in one half of a DNA repair enzyme is to be born one step closer to cancer; target cancers appear earlier and more frequently. Many early studies note the increased incidence of breast cancer with BRCA1 and BRCA2 germline mutations carriers: over 80% by age 70. (Ford et al. 1998). They also give the increased risks of ovarian cancer: for BRCA1, 39% by age 70, and for BRCA2, 11% by age 70 studied 1915 patients with ovarian cancer and detected germline mutations in BRCA1 and BRCA2, RAD51B, Rad51D, PALB2, BARD1, BRIP1 (the HR repair pathway), as well as the genes involved in Lynch Syndrome. (Antoniou et al. 2003; Norquist et al. 2016).

Penetrance is the phenotypic expression of underlying genetic aberrations. Why does one woman with a BRCA1 mutation exhibit breast and/or ovarian cancer while another woman with the SAME mutation does not? Penetrance is influenced by environmental and genetic factors. For example, epidemiologic studies have shown that breast feeding and tamoxifen use decrease the risk of manifesting breast cancer in carriers of BRCA1 mutations. (Friebel, Domchek, and Rebbeck 2014). This same review and meta-analysis shows that oral contraceptives use decreases risk for ovarian cancer in BRCA1 and BRCA2 mutation carriers. Other known risk factors can interact with individuals who have an inherited gene mutation to increase the risk. In other words, women with BRCA and other hereditary gene mutations, are at least as susceptible to other reproductive, environmental, or inflammatory risk factors as women who do not have mutations. This would be expected with BRCA mutation carriers exposed to talcum powder products.

Factors that decrease penetrance may be external or environmental factors, as mentioned above, or may be intrinsic factors, genetic, or epigenetic. Rebbeck et al. demonstrated that the location of the mutation in these huge BRCA genes is a determinant of risk of manifestation of breast and/or ovarian cancer. (Rebbeck et al. 2015). Genetic and epigenetic modifiers became the focus of the CIMBA (Consortium of Investigators of Modifiers of BRCA1/2). (CIMBA et al. 2007). This international consortium of sixty groups of researchers are identifying genetic modifiers to BRCA breast and ovarian cancer risks as single nucleotide polymorphisms (SNPs) in nonBRCA genes. (Ding et al. 2012; Ramus et al. 2012). Such SNPs modify penetrance. Epigenetic changes such as methylation in promoter regions of genes also affect risk of ovarian cancer development.

EPIDEMIOLOGICAL STUDIES

The first epidemiological study was published in 1982 by Cramer, et al, Cancer (1982) 50:372 “Ovarian Cancer and Talc: A Case-Control Study.” (D. W. Cramer et al. 1982). Since that time, there have been numerous additional epidemiological studies.

The Meta-analyses and Pooled Study

Harlow et al, 1992:
This study (of which Cramer is a coauthor) offers the first meta-analysis of the perineal talcum powder use and risk of ovarian cancer in their case-control study of 235 Boston-area women hospitalized in ten area hospitals. Controls were selected from the population and generated from "townbooks" by random number generation selecting the book page and age matched. "Ever" perineal talcum powder use vs none generated a OR of 1.5 (95% CI 1.0-2.1). The meta-analysis follows:

Table 6. Odds Ratios With 95% Confidence Intervals of Ovarian Cancer in Relation to Any Perineal Exposure to Talc as Reported in Previous Epidemiologic Studies

	Cases		Controls			
Author(s) (year)	Total	Talc exposure	Total	Talc exposure	Crude OR	95% CI
Cramer et al[4] (1982)	215	92 (42.8%)	215	61 (28.4%)	1.9	1.3–2.9
Hartge et al (1983)*	135	67 (49.6%)	171	100 (58.5%)	0.7	0.4–1.1
Whittemore et al[5] (1988)	188	98 (52.1%)	539	248 (46.0%)	1.4	0.9–2.0
Harlow and Weiss[6] (1989)†	116	49 (42.2%)	158	64 (40.5%)	1.1	0.7–2.1
Booth et al[7] (1989)	217	141 (65.0%)	434	256 (59.0%)	1.3	0.9–1.9
Harlow et al (1992) (current study)	235	114 (48.5%)	239	94 (39.3%)	1.5	0.9–1.8
All studies‡	1106	561 (50.7%)	1756	823 (46.9%)	1.3	1.1–1.6

The authors conclude that "there is an association, albeit modest, between ovarian cancer and peritoneal talc use" They state that this association may be due to asbestos contamination in talcum powder produced before 1976. This study was supported by an NCI grant. (Harlow et al. 1992).

Gross and Berg, 1995
These investigators analyzed 9 case-control studies (D. W. Cramer et al. 1982; Hartge et al. 1983; Whittemore et al. 1988; Booth, Beral, and Smith 1989; Harlow and Weiss 1989; Y. Chen et al. 1992; Harlow et al. 1992; Rosenblatt, Szklo, and Rosenshein 1992; Tzonou et al. 1993) and combined those studies with preliminary (and mathematically manipulated) data from Hankinson et al's 1993 report on the Nurses' Health Study. The Nurses' Health Study was not completed until 1996; talc use was not queried in the first 8 years of the study. By Gross' and Berg's estimate the RR of "ever genital talc use" vs "never" use is 0.6 (95%CI 0.38-1.02). In fact, that is a low RR as the Nurses' study showed and overall RR of ever vs never use and epithelial ovarian cancer of 1.09 (95% CI 0.86-1.37). (Gertig et al. 2000, see below).

192 *Gross and Berg*

TABLE 3. Results of the Meta-Analyses

Analysis	Studies used	*Q* (degrees of freedom)	RR (95% CI)
Crude risk, both tumor types	All	11.884 (8)	1.27 (1.09–1.48)
Adjusted risk, both tumor types	CRAM, HART, WHIT, HAR1, HAR2, CHEN, and TZON	9.043 (6)	1.31 (1.08–1.58)
Crude risk, epithelial tumors	HART, WHIT, BOOT, HAR2, ROSE, CHEN, and TZON	7.19 (6)	1.20 (1.01–1.44)
Adjusted risk, epithelial tumors	HART, WHIT, HAR2, CHEN, and TZON	7.598 (4)	1.29 (1.02–1.63)

The authors demonstrated that “all meta-analyses arrive at relative risks greater than 1.0 with 95% confidence intervals excluding the null.” Despite these findings, the authors conclude that “existing evidence linking talc exposure to an increased risk of ovarian cancer cannot be viewed as scientifically conclusive”. A dose response relationship is not demonstrated. This study was supported by Johnson and Johnson. (Gross and Berg 1995).

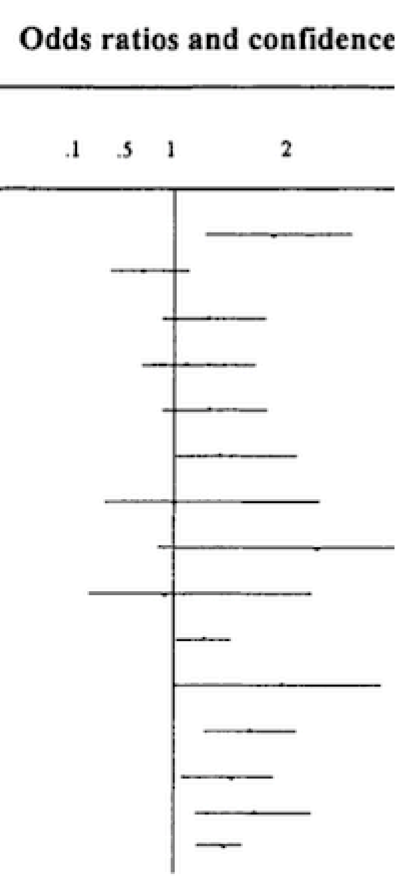
Cramer et al, 1999

In 1999, Cramer et al (with Harlow as a coauthor) published a new case-control study of 563 epithelial ovarian cancers, including 86 serous borderline tumors. Controls were 523 women. No increased risk of ovarian cancer was seen in never users of powder vs non-genital powder users. For those who never used or had nongenital powder use vs any genital use, the odds ratio was 1.60 (95% CI 1.18-2.15) for development of ovarian cancer. Adjustments for age, community, parity, oral contraceptive use, BMI, and family history of breast or ovarian cancer were made.

These authors then did meta-analysis with the following results:

Risk of ovarian cancer with perineal exposure to talc from key epidemiologic studies.

Author	Cases Total n	Cases Exposed (%)	Controls Total n	Controls Exposed (%)	Crude OR (95% CI)
Cramer *et al.* (1982)	215	(42.8)	215	(28.4)	1.9 (1.3-2.8)
Hartge *et al.* (1983)	135	(49.6)	171	(58.5)	0.7 (0.4-1.1)
Whittemore *et al.* (1988)	188	(52.1)	539	(46.0)	1.3 (0.9-1.8)
Harlow and Weiss (1989)	116	(42.2)	158	(40.5)	1.1 (0.7-1.7)
Booth *et al.* (1989)	217	(65.0)	434	(59.0)	1.3 (0.9-1.8)
Harlow *et al.* (1992)	235	(48.5)	239	(39.3)	1.4 (1.0-2.1)
Rosenblatt *et al.* (1992)	77	(87.0)	46	(88.0)	1.0 (0.3-3.0)
Chen *et al.* (1992)	112	(6.2)	224	(2.2)	2.9 (0.9-9.4)
Tzonou *et al.* (1993)	189	(3.2)	200	(3.5)	0.9 (0.3-2.7)
Purdie *et al.* (1995)	824	(56.7)	860	(52.0)	1.2 (1.0-1.5)
Shushan *et al.* (1996)	200	(10.5)	408	(5.6)	2.0 (1.0-3.6)
Cook *et al.* (1997)	313	(50.8)	422	(39.3)	1.6 (1.2-2.1)
Chang and Rish (1997)	450	(44.0)	564	(35.6)	1.4 (1.1-1.8)
Cramer *et al.* (1999)	563	(27.0)	528	(18.2)	1.7 (1.2-2.2)
Summary odds ratio (95% confidence interval)					1.4 (1.2-1.5)



Cramer et al. conclude that "a consistent association between talc and ovarian cancer appears unlikely to be explained by recall bias or confounding" (page 356). This study, too, was supported by a grant from the National Cancer Institute. (Cramer 1999).

Huncharek et al, 2003

Sixteen case control studies (Booth, Beral, and Smith 1989; C.-J. Chang et al. 2017; Y. Chen et al. 1992; Cook, Kamb, and Weiss 1997; D. W. Cramer et al. 1982; D. W. Cramer 1999; Godard et al. 1998; Harlow and Weiss 1989; Ness et al. 2000; Purdie et al. 1995; Rosenblatt, Szklo, and Rosenshein 1992; Tzonou et al. 1993; Whittemore et al. 1988; Wong 1999) were found to be homogeneous and delivered 11,933 subjects (4959 cases). Pooled meta-analysis of ever perineal talcum powder use versus no exposure "yielded a summary relative risk of 1.33 with a 95% confidence interval of 1.16-1.45, a statistically significant result suggesting a 33% increased risk of developing ovarian cancer". No dose response was found. However, the study did not collect the necessary data to permit this determination. Huncharek et al. spend the rest of the paper dismissing their result as NOT supporting an association between talc and ovarian cancer. According to the disclosure, this research was partially supported by the Marshfield Medical Research Foundation. There was no mention of financial support from Johnson & Johnson or Imerys (although disclosed in a 2007 paper by the same authors – Huncharek 2007).

Langseth et al 2008

The Langseth study drew data from The International Agency on Cancer Research (IARC) review of the literature, published as a Monograph in 2010 (which classified non-asbestiform talc as possibly carcinogenic)[3], but did not provide a comprehensive report on this review or the findings. IARC was founded in 1965 and comprises investigators from 25 countries who "promote international collaboration in cancer research" (IARC.fr website). Langseth found an OR of 1.35 (95% CI1.26-1.46), suggesting a statistically significant increase in ovarian cancer risk and concluded that "epidemiological evidence suggests that the use of cosmetic talc in the perineal area may be associated with ovarian cancer risk. Langseth commented in the high degree of consistency in the studies reviewed and proposed that "the mechanism of carcinogenicity may be related to inflammation."

See insert below.

[3] IARC defines Group 2B as follows: Group 2B: The agent is possibly carcinogenic to humans. This category is used for agents for which there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals. It may also be used when there is inadequate evidence of carcinogenicity in humans but there is sufficient evidence of carcinogenicity in experimental animals. In some instances, an agent for which there is inadequate evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals together with supporting evidence from mechanistic and other relevant data may be placed in this group. An agent may be classified in this category solely on the basis of strong evidence from mechanistic and other relevant data. (IARC 2012).

Langseth et al, 2008

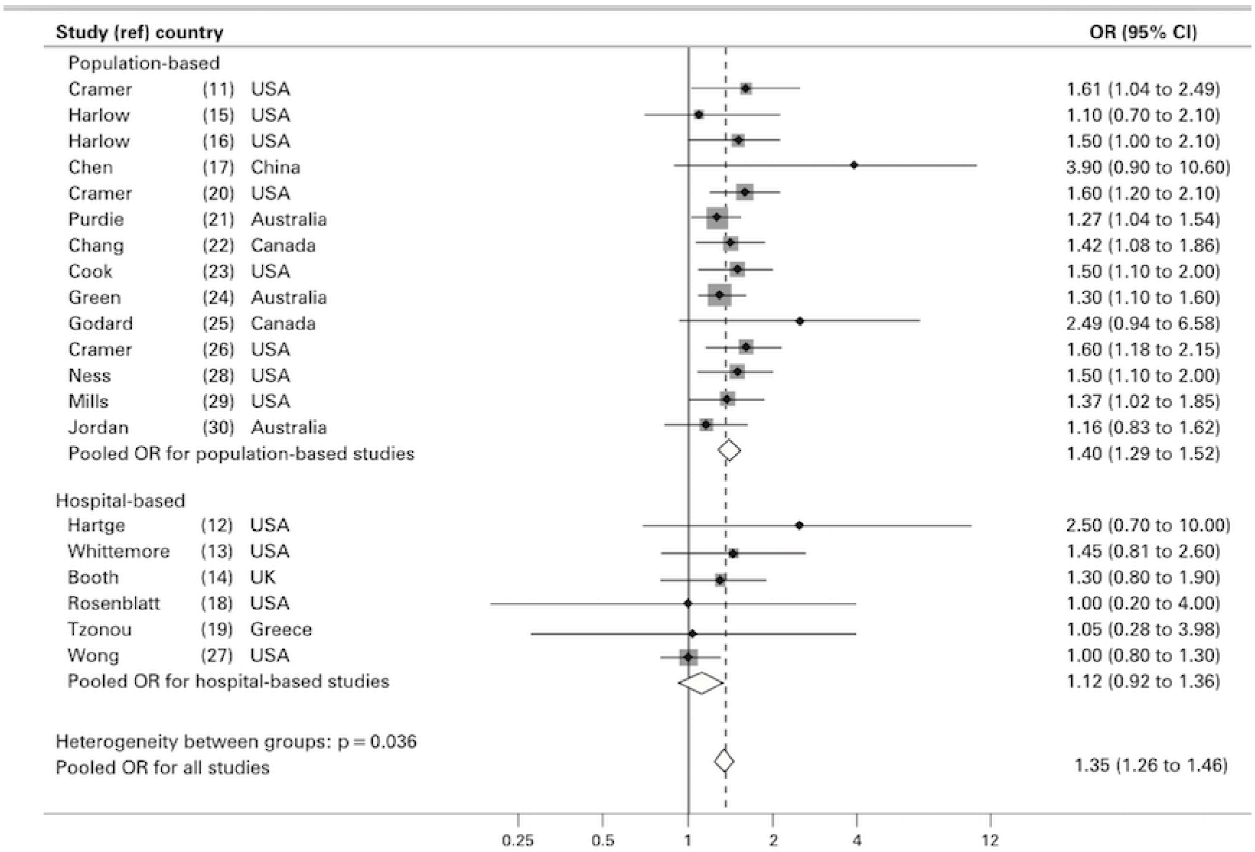


Figure 1 Results from case-control studies contributing data on perineal talc use and ovarian cancer. Results are presented as odds ratios (ORs) anc their corresponding confidence intervals (95% CIs) and represented by squares and lines, respectively. Results are separated in 14 population-basec and six hospital-based case-control studies. Pooled ORs for all population-based studies combined and all hospital-based studies combined are given OR pooling by fixed effect models (Mantel-Haenszel method).

11=Cramer et al, 1982
15=Harlow and Weiss, 1989
16=Harlow et al, 1992
17=Chen et al, 1992
20=Cramer and Xu, 1995
21-Purdie et al, 1995
22=Chang and Risch, 1997
23=Cook et al, 1997
24=Green et al, 1997
25=Godard et al, 1998
26=Cramer, 1999
28=Ness et al, 2000
29=Mills, et al, 2004
30=Jordan et al, 2007
12=Hartge et al, 1983
13=Whittemore et al, 1988
14=Booth et al, 1989
19=Tzonou et al, 1993
27=Wong et al, 1999
18=Rosenblatt et al, 1992

The Langseth et al study was financed by the Cancer Registry of Norway.

Terry et al, 2013
The Ovarian Cancer Association Consortium, an international, multidisciplinary group, investigates factors related to ovarian cancer development, including case-control studies and identification and analysis of genes associated with cancer risk. It is supported, in part, by the Ovarian Cancer Research Fund, the United States National Cancer Institute, and Cancer Research UK. Raw data from the following studies were pooled and analyzed: Rosenblatt et al, 2011 (including previously unpublished additional patients and data), Goodman et al, 2008 (previous unpublished data on powder use), Lo-Ciganic et al, 2012 (previously unpublished data on powder use), Moorman et al, 2009 (adding previously unpublished patients and data), Cramer et al , 1999 (with additional patient data), Pike et al, 2004 (previously unpublished powder use data), Merritt et al, 2008 (with additional patient data), and Chang et al, 1997 (including previously unreported patient data). Cofounders adjusted for include age, oral contraceptive use and duration, parity, tubal ligation, BMI, race/ethnicity. The cases were 8525 cases of ovarian, fallopian tube, and primary peritoneal cancer, reflecting the recognition, in the decade of the 2000s, of the overlap and similarity and possible common etiology of these differently named cancers. In this study, 31% of cases used genital powder, as opposed to 25% of controls. Comparing ever users of genital powder with never users, the OR was 1.24 (95% CI 1.15-1.33). Similar results were seen for genital use vs non-genital use of powder. Risks were stronger for patient with BMI < 30. There was no association with parity, OC use, tubal ligation status, or menopausal status. Histologic break down of the cases showed significant increased risk in both borderline (OR 1.29 [95% CI 1.14-1.48]) and invasive cancers (OR 1.21, [95%CI1.12-1.32]). Significant increased odds ratios with genital powder use were seen for invasive serous, endometrioid and clear cell tumors, but not invasive mucinous tumors. (Terry et al. 2013).

Penninkilampi and Eslick, 2017
The most recent meta-analysis is from two authors at the University of Sydney in New South Wales, Australia. The authors analyzed 24 case-control studies and 3 cohort studies on perineal talcum powder use and risk of development of ovarian study, excluding studies of fewer than 50 cases and duplicated published data. A total of 14,311 cases of ovarian cancer were included. Quality of the component studies were scored on the Newcastle-Ottawa Scale; none scored perfect, but the lowest score was 5/10, so none were excluded. Long term talcum powder use was judged greater than 10 years and was associated with an increase in ovarian cancer risk of OR=1.25 (95% confidence interval (CI) 1.10-1.43). (Lifetime applications of perineal talc of 3600 times roughly correlates with 10 years use; increased risk of ovarian cancer was found with fewer and more applications than 3600.) "Any perineal talc use was associated with any serous, serous invasive, serous borderline and endometrioid subtypes of ovarian cancer (Figure 2c)." This is the largest meta-analysis to date and continues to support the association of perineal talc use with increasing the risk of epithelial ovarian cancers. (Penninkilampi and Eslick 2018).

The Prospective Cohort Studies

There are three true prospective cohort studies looking at genital talcum powder use to perineum, diaphragms or menstrual pads or such use in some combination.

Gertig 2000
The Nurses' Health Study (Gertig et al, 2000) is a 20-year duration study (1976-1996) of 78,630 nurses age 30-55 (in 1976) in the USA. Perineal talcum powder use was first queried in 1982. The cohort answered questionnaires every other year. Ovarian cancer developed in 307 nurses. The relative risk (RR) for ever use of talcum powder and development of any epithelial ovarian cancer was 1.09 (95% CI 0.86-1.37). Invasive serous ovarian cancer demonstrated a statistically significant elevated multivariate RR of 1.40 (95% CI 1.02-1.9) (controlled for age, parity, duration of oral contraceptive use, BMI, tubal ligation, smoking and menopausal status). No other histologic group (all serous including borderline tumors, endometrioid or mucinous tumors) showed elevated risk with appropriate confidence intervals. Within this study there was no dose-response demonstrated, although P for trend was 0.5. For users over 45 years old in 1982 RR for serous ovarian cancer was 1.51 (95% CI 1.07-2.15). No such increased relative risk for any ovarian cancer type was seen for those under 45 in 1982. Gates (2010) continues the analysis of the NHS, finding no increased risk of any subtype. (Gertig et al. 2000).

Houghton 2014
The Women's Health Initiative Study was published by Houghton et al in 2014. This study of 61,576 postmenopausal women (age 50-79) showed ever-talc-use (perineal, diaphragm, pad) was not associated with statistically significant increased risk of development of any ovarian cancer contrasted to never-use (Hazard ratio=1.12 [95% CI 0.92-1.23]). There were 429 incident cases of ovarian cancer over the 12+ years of this study. In this study, talc use in any form was combined, no histologic information was obtained, and information on frequency of use was not obtained. (Houghton et al. 2014).

Gonzalez 2016
Gonzalez et al, 2016 studied a cohort of sisters or half-sisters of breast cancer patients in the USA. After exclusions, (BSO, missing data), 41,654 women were followed a median of 6.5 years during which 135 ovarian cancer, 5 fallopian tube cancers and 4 peritoneal cancers were diagnosed. Eight other cancers were likely from one of these three sites. (Only 96 cases of cancer were verified by medical record or death certificate review; all other were solely patient-reported at annual questionnaire responses.) At entry, the participants completed questionnaires regarding genital talc use as powders or spray and its frequency and douching. Perineal powder use was inversely associated with the development of ovarian-type cancer (Hazard ratio=0.73 (95% CI 0.42-1.1). Douching during the 12 months prior to study entry was associated with an increased risk of ovarian cancer (HR=1.8 [95% CI 1.2-2.8]), while combined talc and douching in the 12 months antecedent to study entry resulted in an HR=1.8 (95%CI 0.81-3.9). The authors acknowledge that they cannot know which powders contained talc and admit "powder has changed over time…" Additional limitations include small numbers, failure to ask questions about frequency or duration of powder usage, and short-term follow-up. With an expected latency period of over twenty years, this study would not pick up all cases. All of these deficiencies result in a failure to capture the true risk. (Gonzalez et al. 2016).

The Case-Control Studies

Cramer et al.'s landmark 1982 case control study looked at perineal talcum powder use in 215 white patients with epithelial ovarian cancer matched by age, race, and residence to 215

community women. These 215 cases included 39 borderline tumors. All pathology was histologically reviewed. Cases and controls were interviewed as to talc exposure from surgical glove, diaphragm use, and perineal use and/or dusting menstrual pads. Talc use varied between cases (42.8%) and controls (28.4%). Any perineal talc exposure showed an adjusted relative risk of ovarian cancer of 1.92 (95% confidence limits 1.27-2.89). (This relative risk was adjusted for parity and menopausal status.)

In the ensuing thirty-five years, at least 24 case-control studies looking at the association of talc and ovarian cancer, both invasive and borderline, have been published. Studies vary in design quality and size, but show a consistent increased risk of ovarian cancer with genital talcum powder use. That data summary follows and is attached as Exhibit B.

Based on the limitations of the cohort studies and the variances in design and size of the case-control studies, I based my opinions largely on the meta-analyses, particularly Penninkilampi's most recent study. In my opinion, meta-analysis provides the most reliable evidence in this situation. The large number of overall cases (>14,000) in this study improves the power to detect a relatively small effect size. The authors agree: "As it stands, a meta-analysis of observational studies, such as the present study provides the highest level of evidence practically feasible for this research question." (Penninkilampi and Eslick 2018).

In my opinion, meta-analysis is the most valid and reliable way to study an issue like ovarian cancer, that is relatively rare and requires a long study period to detect. The cohort studies were not designed to specifically to look at talcum powder. Instead, the use of talcum powder is only one of many queries. All of the cohort studies are limited by failure to obtain complete information, lack of power, selection bias, and short follow-up.

When looking at epidemiological studies with a critical eye and in their totality, they demonstrate a clear, consistent, and statistically significant increased risk of EOC (approximately 20-50%) with the genital use of talcum powder products. This risk is replicated over a large number of case-control studies, one cohort study, and all meta-analyses/pooled analyses over several decades. Recall and confounding bias in case-control studies appear to have minimal impact. (Penninkilampi and Eslick 2018; Langseth et al. 2008). There appears to be no significant publication bias. (Berge et al. 2017; Penninkilampi and Eslick 2018).

MECHANISM

How Talc Particles Reach the Tube, Ovary and Peritoneum

In 1971, Henderson, et al of Cardiff, Wales published their findings of talc deeply embedded in ovarian cancers. (Henderson et al. 1971)(Talc was also demonstrated in cervical cancers, endometrial cancers and non-diseased ovaries.) Ten years previously, Egli and Newton had demonstrated that carbon particles instilled in the posterior vaginal fornix would be "flushed" from the fallopian tubes removed transabdominally (No propulsive force of talc introduction was used in this study). (Egli and Newton 1961). Glove powder from vaginal examination can be found in the peritoneal cavity one to four days after exam. (Sjösten, Ellis, and Edelstam 2004). Based on the studies of Egli and others, Dr. J. Donald Woodruff began to postulate that "some agent enters the peritoneal cavity through the fallopian tube, irritates the pelvic peritoneum,

produces proliferation and with an added unknown ingredient results in the development of malignancy." (Woodruff 1979). Dr. Woodruff emphatically encouraged more scientific attention to agents introduced into the vaginal canal. This paper is the text of a lecture delivered in October of 1978. Drs. Longo and Young expressed their concerns about talc and pathogenesis of ovarian cancer and also encouraged further study of the risks of cosmetic talc use in women. (D. L. Longo and Young 1979). Although I reviewed the small number of articles that dispute talcum powder's ability to reach the tubes and ovaries, I rejected these claims. It is a universally accepted phenomenon by the gynecologic medical community, well documented in the scientific and medical literature, that the female genital tract functions as a conduit for foreign material to enter the peritoneal cavity. This is the process that occurs with talcum powder.

How Inflammation Leads to Mutagenesis and Cancer

"Prolonged chemical exposures, persistent foreign bodies, recurrent acute inflammation or certain pathogens are all causes of chronic inflammation." (Ferguson, Chronic inflammation and mutagenesis, 2010). In this milieu, cytokines are generated, particularly TNF-alpha and IL-1beta. These cytokines generate reactive oxygen species (ROS) and reactive nitrogen species (RNS). ROS are incompletely reduced oxygen compounds that travel through the cell hungrily seeking electrons to steal or donate. These TNF-alpha radicals are potent mutagens and are comparable to the effects of ionizing radiation. (Yan et al. 2006; Yan, Peng, and Li 2009) (Yan methods described in 2009 book chapter). These ROS radicals cause DNA breaks, DNA adducts as well as having epigenetic effects (for example, lysine acetylation in chromosomal histones). The generation of TNF-alpha is DNA synthesis dependent and occurs in the macrophage (a WBC first responder in inflammation). (Liou and Storz 2010; Ferguson 2010; Yan 2011).

Inflammation and its involvement in the etiology and development of many types of cancer, has been studied extensively. (Klampfer 2011).

The inflammatory basis for cancer development is also supported by studies showing a reduced risk of cancer with the use of anti-inflammatory agents. (Burn et al. 2011).

This inflammatory cascade has been shown to occur in the pathogenesis of EOC as well. (Shan and Liu 2009; Saed, Morris, and Fletcher 2018; Saed, Diamond, and Fletcher 2017, 2017; Saed et al. 2018; Khan et al. 2011; Trabert et al. 2014).

In the "normal" cell, DNA damage is either repaired or the damaged cell is directed via the P53 pathway to apoptosis. Yan et al (2006) found more DNA aberrations in homozygous p53-negative cells of colon cancer origin. (Yan et al. 2006). Gates et al (2008) document absence of some DNA repair mechanisms in patients who are genital talc exposed compare to controls in New England Case Control Study as well as the Nurses' Health Study. (Gates et al. 2008).

In an *in vitro* study by Shukla (2009), crocidolite asbestos and non-fibrous talc caused expression of different genes in mesothelial cells and ovarian epithelial cells producing inflammatory cytokines. (Shukla et al. 2009).

Buz'Zard transformed normal ovarian epithelial cells to malignant cells by talc exposure. (2007). (Buz'Zard and Lau 2007). Her methods are supported by the works of Yan et al and Khan et al.

Harper and Saed have recently reported a mechanism by which talc enhances the pro-oxidant state in normal [ovarian and tubal] and ovarian cancer cells, through inductions of gene point mutations (SNPs) in key oxidant enzymes, altering their activities. (Harper and Saed 2019).

Multiple investigators have looked at the effects of aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs) on the risk of developing ovarian cancer. Although somewhat inconsistent, data regarding NSAID and aspirin use suggest a protective effect (results of these studies are inconsistent. (Murphy et al. 2012; Trabert et al. 2014, 2019). In a case control study, use of NSAIDs increased the risk of ovarian cancer. (A. H. Wu et al. 2009). Trabert et al pooled 12 population based case-control studies regular aspirin use decreased the risk of ovarian cancer, both low dose and high dose. Daily high dose NSAIDs decreased ovarian cancer risk. (Trabert et al. 2014). Trabert et al looked at 15 prospective cohort studies from North America and Europe and found no effect of aspirin or NSAIDs on ovarian cancer risks. (Trabert et al. 2019). No study found an effect on ovarian cancer of acetaminophen use, an analgesic, antipyretic with no anti-inflammatory properties. Dixon et al found no correlation with pre-diagnosis aspirin or NSAID use and survival duration after the diagnosis of ovarian cancer. (Dixon et al. 2017)

ASBESTOS AND OTHER CONSTITUENTS

There is evidence from medical literature that talcum powders are not pure talc, but contain impurities including asbestos. (Cralley, Key, et al. 1968; Cralley, Keenan, et al. 1968; Rohl et al. 1976; Werner 1982; Lockey 1981; Paoletti et al. 1984; Blount 1991). I have also seen evidence of testing of Johnson and Johnson talcum powder products by Dr. William Longo demonstrating the presence of asbestos and fibrous talc in talcum powder product samples. (W. E. Longo and Rigler 2018). In addition, I have seen numerous Johnson and Johnson testing results showing the presence of asbestos in their talcum powder products. (Exhibit 28, Deposition of John Hopkins, Ph.D., MDL No. 2378, 2018; Exhibit 47, Deposition of Julie Pier, MDL No. 2738, 2018).

Asbestos is well known to be one of the most potent human carcinogens. The International Agency for Research in Cancer (IARC) has determined that asbestos causes mesothelioma and cancer of the lung, larynx, and ovary. IARC 2012. According to IARC, all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite and talc containing asbestiform fibers (fibrous talc) are carcinogenic. The IARC Working Group found that a “causal association between exposure to asbestos and cancer of the ovary was clearly established, based on five strongly positive studies in women with heavy occupational exposure to asbestos. (Acheson et al. 1982; Wignall and Fox 1982; Germani et al. 1999; Berry, Newhouse, and Wagner 2000; Magnani et al. 2008; IARC 2012). The IARC 100C Working Group was convened in 2009, with results published in 2012.

In 2011, Camargo et al, published a meta-analysis of epidemiologic studies of ovarian cancer in asbestos exposed women. (Camargo et al. 2011). Their finding of a standardized mortality ratio (SMR) of 1.77 for risk of ovarian cancer mortality (95% confidence intervals 1.37-2.28) corroborate the finding of the IARC Working Group.

Distinction of peritoneal mesothelioma and ovarian carcinomatosis can be difficult. Even with such discrimination, asbestos increases ovarian cancer risk. (Alison Reid, Klerk, and Musk 2011).

"Consumer products are the primary sources of exposure to talc for the general population. Inhalation and dermal contact (i.e. through perineal application of talcum powders) are the primary routes of exposure". (IARC 2012). The mechanism of carcinogenesis of asbestos is the same as discussed above: induction of the inflammatory cascade resulting in mutagenesis either through a direct or indirect mechanism. Although migration/transport through the genital tract is the primary source of exposure with genital talcum powder use, inhalation represents a secondary exposure route. With either route, talcum powder particles can be also absorbed and transported through the lymphatics or blood system to pelvic organs and lymph nodes. The mechanism for the carcinogenicity of asbestos in the ovary and elsewhere provides a plausible biological mechanism by which it can contribute to the carcinogenicity of talcum powder products.

I have also seen evidence of the presence of heavy metals, including nickel, cadmium, and cobalt in Johnson and Johnson talcum powder products. (Exhibit 47, Deposition of Julie Pier, MDL 2738, 2018). Nickel and chromium are Group 1 carcinogens. (IARC 2012). Cobalt is identified by IARC as Group 2b possibly carcinogenic. (IARC 2012). The mechanism of action described by IARC, is inflammatory in nature. These heavy metals likely contribute to the carcinogenicity of talcum powder products by the inflammatory mechanism described at length in this report.

I have reviewed the list of fragrances chemicals contained in Johnson's Baby Powder and Shower to Shower products and the expert report of Dr. Michael Crowley. I agree with Dr. Crowley's opinion that these chemicals likely contribute to the inflammatory properties, toxicity and/or carcinogenicity of these products.

DETERMINATION OF CAUSATION

In 1965, epidemiologist Sir Austin Bradford Hill published his factors for determining causation from associations found in epidemiologic studies. (Hill 1965). These factors have been widely used, but are not considered absolute or required for a causal determination. These considerations have also been elaborated upon for the 21st century by Fedak et al. (Fedak et al. 2015). For a doctor treating patients, knowledge of risk factors and causes of diseases are important for diagnosis, prevention, and treatment of the diseases. In essence, risk factors (associated with a health outcome) can be considered causal when the biological and molecular mechanisms for this relationship are known or predictable based on scientific research. The following are the Bradford Hill considerations and my analysis as they relate to talcum powder products and their relationship with ovarian cancer.

Strength: There is no set magnitude or threshold for ascribing causality. I would maintain that any practice or element that increases the risk of ovarian cancer by ANY consistent percentage is significant. Ovarian cancer is, usually, a fatal disease, not a trivial inconvenience. The increased risk of ovarian cancer in perineal talc users in epidemiologic studies is 1.2-1.5, a 20-50% increased risk.

Consistency: The consistency of the case-control epidemiologic studies the uniformity of the meta-analayses (Harlow et al, 1992, Gross and Berg, 1995, Cramer et al 1999, Huncharek et al 2003, Langseth et al, 2008, the pooled study of Terry et al 2013, and the recent Penninkilampi 2017) is impressive. The studies are from different populations across three continents. The seeming inconsistency with the cohort studies are likely due to lack of power and other study design limitations. (Narod 2016). Strength and consistency are very important to a physician involved in patient care.

Specificity: Bradford Hill noted that different agents may cause more than one disease. Furthermore, any disease may have multiple component causes. "One-to-one relationships are not frequent". (Hill 1965). Certainly, talc causes talcosis and medically induced pleural inflammation. The body of epidemiologic work supports talcum powder's role in risk of epithelial ovarian cancer. For a physician, this consideration is less important than strength of association and consistency.

Temporality: This requirement is met by studies of risk of ovarian cancer for those who used talcum powder versus those who did not. It may take in vitro studies to establish threshold dose exposures. Bradford Hill did not address latency which is another marker of temporality. In the case of talcum powder use and ovarian cancer, the average latency period exceeds twenty years. (Magnani et al. 2008; A. Reid et al. 2014; Okada 2007). Reverse temporality is most unlikely in this case. Temporality is not particularly important to a physician as long as it has been shown to exist.

Biologic gradient: This refers to dose response relationship which is not seen in all of the epidemiologic studies, but is demonstrated in some. (Harlow et al. 1992; S. Chang and Risch 1997; Daniel W. Cramer et al. 2016; Schildkraut et al. 2016; Terry et al. 2013; Penninkilampi and Eslick 2018). In the studies that failed to demonstrate a clear dose response, many simply did not have adequate data to assess. With genital talcum powder use, quantifying exposure is challenging in terms of measuring the exact amount used in each application, the amounts that migrate or are transported through the genital tract, the amount inhaled, and the amount absorbed through the vaginal mucosa. It is also impossible to measure how much of each constituent is present in any application. In vitro studies would help clarify dose response relationships and mechanisms. To a physician, dose response can be helpful when determining causality, but not essential.

Plausibility: The growing body of evidence from in vitro studies enhance the plausibility of talcum powder's role in the causation of ovarian cancer. The talcum powder reaches the tubes, ovaries, and peritoneum by migration/transport of particles as described earlier in this report Once there, these particles create a hostile inflammatory environment of reactive oxygen and reactive nitrogen species capable of causing mutagenesis/carcinogenesis. This general mechanism is not only plausible, but accepted widely - even though the details at the molecular level are still being clarified. I placed a great deal of importance on the mechanism consideration and I find it compelling.

Coherence: As Bradford Hill stated, assessing causation "should not seriously conflict with the generally known facts of natural history and biology of disease". (Hill 1965). This consideration has been satisfied, since talcum powder and its causal relationship with ovarian cancer is compatible with our knowledge of cancer and cancer processes.

Experiment: Sir Bradford Hill discussed this point as an experimental change in the epidemiologic milieu which mitigated the statistical finding. Fedak et al interpret this point in a more contemporary way: biochemical, in vitro experiments and laboratory investigation of genetic and epigenetic pathways. (Fedak et al. 2015). In this context, there is a growing body of evidence to support the biologic, genetic and epigenetic consequences to the ovarian epithelial cell with talcum powder exposure. (Shukla et al. 2009; Fletcher, Nicole, Memaj, Ira, and Saed, Ghassan 2018; Saed, Morris, and Fletcher 2018; Buz'Zard and Lau 2007).

Analogy: Sir Bradford Hill suggested the analogy of rubella and thalidomide causing birth defects in a similar fashion. I would suggest the analogy of asbestos causing ovarian cancer and mesothelioma or HPV causing cervical cancer.

I give precedence to strength of association and consistency as most important factors. If these are met, I judge plausibility and experiment next in importance.

Cornstarch as a safer alternative

Talc has been known to be more inflammatory and toxic than starch products for decades. (Eberl and George 1948). In addition, there is no epidemiological evidence linking cornstarch to ovarian cancer. (S. Chang and Risch 1997; Daniel W. Cramer et al. 2015; Cook, Kamb, and Weiss 1997). Whysner and Mohan reviewed the literature regarding talc and cornstarch and their relationship to epithelial ovarian cancer. The authors concluded that: 1) due to the chemical nature of cornstarch, a biological mechanism by which cornstarch could cause ovarian cancer is implausible; 2) epidemiologic studies have found no association between cornstarch and ovarian cancer; and 3) no increased risk of ovarian cancer from perineal cornstarch use is predicted. (Whysner and Mohan 2000).

Conclusions

In my opinion, talcum powder products cause epithelial ovarian cancer. This opinion is based on my assessment of the totality of the epidemiologic data presented in the medical and scientific literature, the biologic mechanism, and the credible presence of known carcinogens in the products. This assessment was made by analyzing and weighing the extensive evidence in the context of Bradford Hill considerations.

Summary of my opinions:

1. Johnson and Johnson talcum powder products cause the development and progression of epithelial ovarian cancer.
2. There is credible evidence that Johnson and Johnson baby powder products contain asbestos. Asbestos and fibrous talc cause epithelial ovarian cancer. Heavy metals and

fragrance chemicals added to the products can also contribute to the carcinogenicity of Johnson & Johnson Baby Powder and Shower to Shower products.

3. Talc and asbestos create an inflammatory pro-carcinogenic environment in the human body, the mechanism for epithelial ovarian cancer development and progression.
4. Perineal application of talcum powder products results in the tubal and intraperitoneal deposition of talc and asbestos by migration and transport through the genital tract. Inhalation is a secondary route of exposure.

I reserve the right to amend or modify the report as new information becomes available.

I have not testified in litigation over the previous 4 years. I am charging $600 per hour for my work on this matter. Additional materials I considered are attached as Exhibit C.

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Exhibit A

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1973: B.A. Biology, University of North Carolina, Greensboro. North Carolina
1977: M.D., University of North Carolina. Chapel Hill, North Carolina

SCHOLASTIC HONORS:

1974 Mosby Award
1976 Merck Award
1976 Student Aptitude Award, North Carolina Society of Obstetrics and Gynecology
1976 Alpha Omega Alpha, University of North Carolina School of Medicine
1977 American Medical Women's Association Citation of Scholastic Achievement

POSTGRADUATE TRAINING:

1977-1978: Internship, Obstetrics and Gynecology, UTHSCSA, San Antonio, Texas
1978-1981: Residency, Obstetrics and Gynecology, UTHSCSA, San Antonio, Texas
1979: Galloway Fellowship, Memorial Sloan-Kettering, NY, NY
1981-1984: Fellowship, Gynecologic Oncology, Duke University Medical School, Durham,NC (1983: American Cancer Society Fellow)

PREVIOUS EMPLOYMENT:

1984-1987: Assistant Professor, Gynecologic Oncology, University of Virginia Medical School, Charlottesville, Virginia
1987-1989: Physician and Sole Proprietor, Gynecologic Oncology, Austin, Texas
1989-1995: Physician and President, Austin Gynecologic Oncology Associates, Austin,TX

1995-2008: Physician and Partner, Southwest Regional Cancer Center, Austin, Texas
2008-2015: Physician Shareholder, Texas Oncology, Austin, Texas

MEDICAL LICENSURE:

Texas Medical Board: F0313 (active)
DEA: AS 1121021 (active)
Texas DPS 40063099 (active)
North Carolina State: 24537 (inactive)
Virginia State: 10103669 (inactive)

BOARD CERTIFICATIONS:

1985 American Board of Obstetrics and Gynecology (lifetime certified, voluntary recertification 1996)
1987 American Board of Obstetrics and Gynecology, Division of Gynecologic Oncology (lifetime certified, voluntary recertification 1996)
2011 Hospice and Palliative Medicine (via ABOG), expires 2021

APPOINTMENTS:

1981-1982 Associate, Obstetrics and Gynecology, Duke University Medical School, Durham, NC
1982-1984 Assistant Professor, Obstetrics and Gynecology, Duke University Medical School, Durham, NC
1984-1987 Assistant Professor, Department of Obstetric and Gynecology, University of Virginia Medical Center, Charlottesville, VA
1997-2000 Renaissance Women's Center Advisory Board, Austin, Texas
1998-2003 Hospice Austin Medical Advisory Board, Austin, Texas
1999-2001 Mediation Committee, Travis County Medical Society, Austin, Texas
2001-2007 Gynecologic Cancer Foundation, Board of Directors
Nominating Committee Chair 2004
2007-2008 Section Chief Ob-Gyn, Seton Medical Center, Austin, Texas
2007-2014 Member Surgical Committee, Seton Medical Center, Austin, Texas
2011-2013 Medical Director of Surgical Services, US Oncology (elected office)
2011-2013 Member, National Policy Board Executive Committee, US Oncology
2011-2015 Member, Managed Care Committee, US Oncology
2011-2015 Member, Pathways Committee, US Oncology

PROFESSIONAL SOCIETIES:

Alpha Omega Alpha (1976-current)
American Cancer Society
1985-1987 Charlottesville-Albemarle Unit
Board of Directors
Executive Committee

1984-1986 Virginia Unit

Board of Directors
Colorectal Cancer Control Project Steering Committee
Finance Committee 1986
Nominating Committee 1986
1987-1988 Austin, Texas Unit
Public Education Chairman
American Congress of Obstetrics and Gynecology (1988-Life Member)
Society of Gynecologic Oncology (1988-lifetime)
Program Committee 1995-1996
Coding Committee 1996-2001
Nominating Committee 2008
Palliative Care Committee 2009-current
Session Moderator-Palliative Care- SGO Annual Meeting-2014
Steering Committee, SGO Genetics Summit-2015
American Academy of Hospice and Palliative Medicine 2010-present

PUBLICATIONS (PEER-REVIEWED JOURNALS) :

Smith, EB, Weed, JC, Tyrey, L and Hamond, CB: "Treatment of Nonmetastatic GTD: Results of Methotrexate-Folinic Acid." *Amer J Obstet Gynecol,* 144:88, 1982.

Smith, EB, Szulman, AE, Hinshaw, W, Tyrey, Surti, U, and Hammond, CB: "Human Chorionic Gonadotropin Level in Complete and Partial Hydatidiform Moles and Nonmolar Abortuses." *Amer J Obstet Gynecol,* 149: 129, 1984.

Smith, EB, Clarke-Pearson, DL, and Creasman, WT: "A VP-16 and Cis-Platinum Containing Regimen for Treatment of Refractory Ovarian Germ Cell Malignancies" *Amer J Obstet Gynecol*, 150:927, 1984.

Smith, EB, Dunnick, R, Nelson, PA and Hammond, CB: "Renal Metastases of Malignant Gestational Trophoblastic Disease with Particular Attention to the Use of Intravenous Urography in Staging." *Gynecol Oncol* 20: 137, 1985.

Barter, J, **Smith, EB**, Szpak,CA, et al: "Leiomyosarcoma of the Uterus: A Clinicopathologic Study of 21 Patients." *Gynecol Oncol* 21:221, 1985.

Puleo, JG, Clarke-Pearson, DL, **Smith, EB**, Barnard, DE, and Creasman, WT: "Superior Vena Cava Syndrome Associated with Gynecologic Malignancy." *Gynecol Oncol* 23:59, 1986.

Taylor, PT, Anderson, WA, Barber, SR, Covell, JL, **Smith, EB**, and Underwood, PB: "The Screening Papanicolau Smear: Contribution of the Endocervical Brush." *Obstet Gynecol* 70:734, 1987.

Anderson, WA, Found, D, Peters, W, **Smith, EB**, Bagley, C and Taylor, PT: "Platinum-Based Combination Chemotherapy for Malignant Mixed Mesodermal Tumors of the Ovary." *Gynecol Oncol* 32: 319, 1989.

Plante, M, **Smith, EB** et al: "The case of a viable pregnancy post vaginal radical trachelectomy followed by combined chemoradiation." *Gynecol Oncol* 123:421, 2011.

PUBLICATIONS (INVITED ARTICLES AND BOOK CHAPTERS):

Creasman, WT, **Smith, EB** and Clarke-Pearson, DL: "Gestational Trophoblastic Disease." *The Female Patient*, 9:66, 1984.

Smith, EB, Clarke-Pearson, DL, and Creasman, WT: "Screening of Cervical Cancer." (Chapter10) *Screening and Monitoring of Cancer*. Basil A Still, ed. John Wiley & Sons; 1985.

Smith, EB and Creasman, WT: "Preinvasive and Invasive Cervical Carcinoma Associated With Pregnancy." *Principles of Medical Therapy in Pregnancy*. N Gleicher, ed. Plenum Publishing Corp. New York, New York. 1985. Revision 1990.

Smith, EB, Hammond, CB, Gore, H and Hertig, A. "Gestational Trophoblastic Disease". *Management of the Patient with Cancer*. 3rd edition. TF Nealon, ed. W. B. Saunders CO, Philadelphia, Pa. 1986.

Smith, EB: "Gynecology for the Urologist." *Adult and Pediatric Urology.* J Gillenwater. ed. Year Book Medical Publishers; 1987. Revision 1991.

INVITED LECTURES:

SGO State of the Art Meeting 2011- Palliative Care

SGO Winter Meeting 2013-Palliative Care

Exhibit B

EXHIBIT A

First author and year	Cases (%talc use)	Controls (%talc use)	OR	95% CI	Dose Response	Comments
Cramer, 1982	215 (43%)	215 (28%)	1.9	1.27-2.89		
Hartge,1983	135	171	0.7	0.4-1.1		hosp, letter only. Only 10 with perineal use
Whittemore, 1988	188 (52%)	539 (46%)	1.45	0.81-2.8	no	perineal use, mixed hosp and population
Harlow, 1989	116	158	2.8	1.111.7	no	LMP only, deodorant powder +/-talc
Booth,1989	235 (68%)	451 (61%)	rare=0.9 weekly=2.0 daily=1.3	0.3-2.4 1.3-3.4 0.8-1.9	no	hosp. path reviewed
Rosenblatt, 1992	77 (91%)	46	1	0.2-4.0		These nmbers are way too small.
Chen,1992	112 (6%)	224 (2%)	3.9	0.9-11.6		also used occupational exposure, only 7 vs 5 total perineal powder users
Harlow, 1002	235 (48.5%)	239 (39.3)	1.5	1.0-21	trend NSS	perineal use
Tzounou,1993	189 (3%)	200 (3.5%)	1.05	0.28-3.98		hosp, hairdye, low usage numbers, Greece
Purdie,1995	824 (57%)	860 (52%)	1.25	1,04-1,54		adj for parity , 17% LMP Austrailia
Shusan, 1996	200 (11%)	406 (5.6%)	seems to be ; simple X2= 0.4			Never/seldom vs mod-a lot, Focus on fertility drugs Israel
Chang, 1997	450 (44%)	564 (35.6%)	all 1.42 LMP 1.24 inv 1.51	1.08-1.86 0.76-2.02 1.13-2.02	duration=borderline frequency=no	no assn with cornstarch, Canada
Cook, 1997	313	422	1.5	1.1-2.0	no	ever powder use, looked at genital deodorant as well
Godard,1998	170 (10.6)	170 (4.7)	2.49	0.94-6.56		perineal use only p=0.066 French Canadians
Wong, 1999	499 (47.8%)	755 (44.9%)	genital+pad 1.1 genital 1.0 pad 0.9	0.7-1.7 0.8-1.3 0.4-2.0	no	

first author, year	cases (% talc use)	controls (%talc use)	OR	95% CI	dose-response	Comments		
Cramer, 1999	563 (45%)	523 (36%)	any genital powder 1.6 perineal talc 1.69	1.18-2.15 1.26-2.27	no			
Ness,2000	767 (55%)	1367 (47%)	genital 1.5 pad 1.6	1.1-2.0 1.1-2.3	no	BTL protective, risk increased witalc on all areas body		
Mills,2004	256 (43%)	1122 (37%)	ever talc 1.37 serous 1.77	1.02-1.85 1.12-1.81	no			
Merritt, 2008	1576 (46%)	1509 (43%)	1.17	1.01-1.36		adjusted OR, decreased with ASA, BIG NUMBERS	Australia	includes LMP, FT, PP
Moorman,2009	143 AA 943 white	189 AA 868 white	1.19 1.04	0.68-2.09 0.82-1.33)				
Rosenblatt, 2011	812	1313	all 1.27 LMP 1.55 inv 1.38	0.97-1.66 1.02-2.37 0.77-2.47	no			
Kurtha, 2012	902 (22%)	1802 (20.9%)	1.4	1.16-1.69		The definitive fertility drug risk paper		
Wu, 2015	hispanics 308 (38%) AA 128 (48%) white 1265 (41%)	380 (28%) 143 (44%) 1868 (30%)	1.56 1.77 1.41	0.8-3.04 1.20-2.62 1.21-1.67		Stat sig more talc use in Aas		
Cramer, 2016	2014 (51%)	2100 (48%)	1.33	1.16-1.52	trend for freq none for duration			
Schildkraut,2016	584 (63%)	745 (53%)	1.44	1.11-1.86	yes			

Exhibit C

"A Survey of the Long-Term Effects of Talc and Kaolin Pleurodesis." *British Journal of Diseases of the Chest* 73 (1979): 285–88. https://doi.org/10.1016/0007-0971(79)90054-8.

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Akhtar, Mohd Javed, Sudhir Kumar, Ramesh Chandra Murthy, Mohd Ashquin, Mohd Imran Khan, Govil Patil, and Iqbal Ahmad. "The Primary Role of Iron-Mediated Lipid Peroxidation in the Differential Cytotoxicity Caused by Two Varieties of Talc Nanoparticles on A549 Cells and Lipid Peroxidation Inhibitory Effect Exerted by Ascorbic Acid." *Toxicology in Vitro: An International Journal Published in Association with BIBRA* 24, no. 4 (June 2010): 1139–47. https://doi.org/10.1016/j.tiv.2010.03.002.

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